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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,566	01/23/2004	Richard Franklin	20342/1202529-US1	3220

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EXAMINER	
HUGHES, ALICIA R	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
04/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/762,566	FRANKLIN, RICHARD	
	Examiner	Art Unit	
	ALICIA R. HUGHES	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,6-9,12-15,17-34,36 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,6-9,12-15,17-34,36 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims and Examination

Claims 2-3, 6-9, 12-15, 17-34, 36 and 50 are pending and the subject of this Office Action.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 28 March 2008 has been entered.

Applicants' argument, filed on 28 March 2008, has been fully considered and it is deemed to be persuasive regarding the previous rejection. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn.

Upon reconsideration of the pending claims, as presented, the following new rejections are applied. They constitute the complete set of rejections being applied to the instant application presently.

Claim Rejections – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-3, 6-9, 12, 17-20, 26-27, 32, 36, and 50 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,194,420 [hereinafter referred to as "Lang"], in view of U.S.

Patent No. 6,221,383 [hereinafter referred to as "Miranda et al"], and in further view of D'Angelo et al.

The teachings of Lang, Miranda et al and D'Angelo et al from this Office's Actions of 19 April 2007 and 28 January 2008 are incorporated herein by reference in total. Applicant argues that the recitation of the new limitation, "thereby reducing the plasma concentration of 3-hydroxy anagrelide compared to a patient orally administered the equivalent amount of anagrelide" in claim 2 is a surprising result that enables one to circumvent adverse side-effects observed from administering anagrelide orally.

The new limitation is a mere function that necessarily flows from the method claimed, because Applicant has elucidated an inherent biochemical mechanism regarding the administration of anagrelide. It is well understood by those of ordinary skill in the art that "the discovery of a previously unappreciated property of a prior art composition or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F. 3d 1342, 1347 (Fed. Cir. 1999). Therefore, the claiming of a new use, a new function, or an unknown property, which is necessarily present in the prior art does not make the claim patentable. Rather, it is incumbent upon the Applicants to "prove that subject matter shown to be in the prior art does not possess characteristics relied on," In re Fitzgerald, 205 USPQ 594, by the presently claimed invention.

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to transdermally administer anagrelide to a patient with thrombocythemia to minimize first liver metabolism and thereby reduce the plasma

concentration of 3-hydroxy anagrelide compared to a patient orally administered the equivalent dosage of the same.

Claims 21-23 and 28-31 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,194,420 [hereinafter referred to as "Lang"] in view of U.S. Patent No. 6,024,975 [hereinafter referred to as "D'Angelo et al"] and in further view of U.S. Patent No. 5,133,972 [hereinafter referred to as "Ferrini et al"].

The teachings of Lang, D'Angelo et al, Ferrini et al in this Office's Actions of 19 April 2007 and 28 January 2008 are incorporated herein by reference in total and as well, the teachings of Atlas Powder Co. and In re Fitzgerald, *supra*, are incorporated herein by reference. Applicant's previous argument from the first rejection is renewed for the present rejection, also.

As noted previously, the new limitation is a mere function that necessarily flows from the method claimed, because Applicant has elucidated an inherent biochemical mechanism regarding the administration of anagrelide. It is well understood by those of ordinary skill in the art that "the discovery of a previously unappreciated property of a prior art composition or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F. 3d 1342, 1347 (Fed. Cir. 1999). Therefore, the claiming of a new use, a new function, or an unknown property, which is necessarily present in the prior art does not make the claim patentable. Rather, it is incumbent upon the Applicants to "prove that subject matter shown to be in the prior art does not possess characteristics relied on," In re Fitzgerald, 205 USPQ 594, by the presently claimed invention.

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to administer anagrelide via a transdermal patch

having a reservoir to a patient with thrombocythemia to minimize first liver metabolism and thereby reduce the plasma concentration of 3-hydroxy anagrelide compared to a patient orally administered the equivalent dosage of the same.

Claims 13-15, 24-25 and 33-34, and 36 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,194,420 [hereinafter referred to as "Lang"] in view of U.S. Patent No. 6,024,975 [hereinafter referred to as "D'Angelo et al"]. and in further view of U.S. Patent No. 4,847,276 [hereinafter referred to as "Yarrington"].

The teachings of Lang, D'Angelo et al, Yarrington in this Office's Actions of 19 April 2007 and 28 January 2008 are incorporated herein by reference in total and as well, the teachings of Atlas Powder Co. and In re Fitzgerald, *supra*, are incorporated herein by reference. Applicant's previous argument from the first rejection is renewed for the present rejection, also.

As noted previously, the new limitation is a mere function that necessarily flows from the method claimed, because Applicant has elucidated an inherent biochemical mechanism regarding the administration of anagrelide. It is well understood by those of ordinary skill in the art that "the discovery of a previously unappreciated property of a prior art composition or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F. 3d 1342, 1347 (Fed. Cir. 1999). Therefore, the claiming of a new use, a new function, or an unknown property, which is necessarily present in the prior art does not make the claim patentable. Rather, it is incumbent upon the Applicants to "prove that subject matter shown to be in the prior art does not possess characteristics relied on," In re Fitzgerald, 205 USPQ 594, by the presently claimed invention.

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art that the administration of 0.1 to 20 mg/kg/day of anagrelide and more particularly, 0.5 to 3 mg of anagrelide daily for at least 1 to 7 days via transdermal delivery would effectively treat essential thrombocythemia.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/

Examiner, Art Unit 1614

/Raymond J Henley III/

Primary Examiner, Art Unit 1614